

wherein said labeled standard DNA comprises a double stranded nucleic acid having a site capable of binding to a solid support on one strand and a detectable label on the other strand;

amplifying said particular region of said analyte nucleic acid which is present in said specimen to prepare said double stranded sample DNA for competitive hybridization, wherein said sample DNA comprises both mutated or polymorphic target DNA and wild-type DNA in an amplifiable amount;

selecting a detection limit for said mutated or polymorphic target DNA, wherein when the detection limit for the target DNA present in said sample DNA is  $A/B$ , the excessiveness of said sample DNA is at least  $B/A$ , and wherein  $A/B$  is the fractional equivalent of the percentage of said mutated or polymorphic target DNA content in the sample DNA;

adding an excessive amount of said sample DNA to said labeled standard DNA, to allow competitive hybridization to take place between said mutated or polymorphic target DNA and labeled standard DNA under conditions which allow for hybridization of at least some of said labeled standard DNA and under conditions wherein non-target sample DNA does not hybridize with said labeled standard DNA, wherein the excessiveness of said sample DNA added to said

labeled standard DNA in the competitive hybridization is calculated as the value of  $B/A$ ,

detecting the hybridized labeled standard DNA by utilizing said detectable label and said site capable of binding to a solid support; and

evaluating the degree of exchange that occurred during competitive hybridization of the complementary strands between said sample DNA and said labeled standard DNA.

14. (Amended) A nucleic acid assay process for identifying and/or quantifying a mutation or polymorphism in a double stranded sample DNA prepared by amplification of a particular region of an analyte nucleic acid which is present in a specimen, comprising the steps of:

providing labeled standard DNA having a nucleotide sequence the same as a mutated or polymorphic target DNA of interest, wherein said labeled standard DNA comprises a double stranded nucleic acid having a site capable of binding to a solid support on one strand and a detectable label on the other strand;

amplifying said particular region of said analyte nucleic acid which is present in said specimen to prepare said double stranded

sample DNA for competitive hybridization, wherein said sample DNA comprises both mutated or polymorphic target DNA and wild-type DNA in an amplifiable amount;

selecting a theoretical value for the amount of said mutated or polymorphic target DNA in said sample DNA, wherein the amount of said mutated or polymorphic target DNA is expressed as A, and the total amount of said sample DNA is B, such that  $A/B$  is the fractional equivalent of the percentage of said mutated or polymorphic target DNA content in the sample DNA;

adding an excessive amount of said sample DNA to said labeled standard DNA, to allow competitive hybridization to take place between said mutated or polymorphic target DNA and labeled standard DNA under conditions which allow for hybridization of at least some of said labeled standard DNA and under conditions wherein non-target sample DNA does not hybridize with said labeled standard DNA, wherein the excessiveness of said sample DNA added to said labeled standard DNA in the competitive hybridization is calculated as the value of  $B/A$ ,

detecting the hybridized labeled standard DNA by utilizing said detectable label and said site capable of binding to a solid support; and

Appl. No. 09/214,723

evaluating the degree of exchange that occurred during competitive hybridization of the complementary strands between said sample DNA and said labeled standard DNA.

Attached hereto is a marked up version showing the changes made to the application by this Reply.